

The AMD ANNALS: A continuous initiative for the improvement of type 2 diabetes care

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ABSTRACT

Aims: Since 2006, the Italian AMD (Associations of Medical Diabetologists) Annals Initiative promoted a continuous monitoring of the quality of diabetes care, that was effective in improving process, treatment and outcome indicators through a periodic assessment of standardized measures. Here, we show the 2022 AMD Annals data on type 2 diabetes (T2D).

Methods: A network involving ~1/3 of diabetes centers in Italy periodically extracts anonymous data from electronic clinical records, by a standardized software. Process, treatment and outcome indicators, and a validated score of overall care, the Q-score, were evaluated.

Results: 295 centers provided the annual sample of 502,747 T2D patients. Overall, HbA1c value $\leq 7.0\%$ was documented in 54.6% of patients, blood pressure $< 130/80$ mmHg in 23.0%, and LDL-cholesterol levels < 70 mg/dl in 34.3%, but only 5.2% were at-target for all the risk factors. As for innovative drugs, 29.0% of patients were on SGLT2-i, and 27.5% on GLP1-RAs. In particular, 59.7% were treated with either GLP1-RAs or SGLT2-i among those with established cardiovascular disease (CVD), 26.6% and 49.3% with SGLT2-i among those with impaired renal function and heart failure, respectively. Notably, only 3.2% of T2D patients showed a Q score < 15 , which correlates with a 80% higher risk of incident CVD events compared to scores > 25 .

Conclusions: The 2022 AMD Annals data show an improvement in the use of innovative drugs and in the overall quality of T2D care in everyday clinical practice. However, additional efforts are needed to reach the recommended targets for HbA1c and major CVD risk factors.

1. Introduction

The prevalence of type 2 diabetes (T2D) continues to rise worldwide, placing an increasing burden on healthcare systems, payers, and providers. Despite the progresses in diabetes care and the availability of new, highly effective treatments, a large gap still persists between the recommendations of guidelines and the outcomes achieved in everyday practice. Furthermore, recent guidelines suggest more stringent targets relative to lipid profile and blood pressure control. Criteria for selecting

the most appropriate glucose-lowering medications for the management of T2D have also changed in view of the evolving evidence, with a paradigm shift from treat-to-target to treat-to-benefit [1].

To improve the current care, monitoring of health and quality of care is recognized as a key strategy [2]. American and European organizations have developed and applied measures to monitor quality of diabetes care and promote continuous quality improvement initiatives [2,3]. However, quality of care indicators should be continuously updated, in order to reflect the acquisition of new knowledge.

Abbreviations: AMD, Associazione Medici Diabetologi; T2D, Type 2 Diabetes; GLP1-RA, Glucagon Like Peptide 1 Receptor Agonist; SGLT2-i, Sodium-glucose Cotransporter-2 inhibitor.

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In Italy, a continuous improvement effort implemented by a network of diabetes clinics has been in place since 2006 [4–6]. The initiative, promoted by the Italian Association of Medical Diabetologists (AMD), involves a wide network of outpatient diabetes clinics operating within the national healthcare system, and allows the routine monitoring of a large set of indicators. The yearly evaluation of patterns of care, the dissemination of results, and their discussion with the participants aims at improving diabetes care, both at the individual clinic level and overall. The initiative has documented important progresses in T2D care during the years [5,6], with a tangible impact on clinical outcomes and related healthcare costs [7]. Recently, the list of indicators adopted to monitor diabetes care has been updated to include new treatment recommendations and new targets for cardiovascular risk factors.

Aim of this paper is to describe up-to-date patterns of care of patients with T2D attending diabetes clinics in Italy.

2. Methods

The methodology of the AMD Annals initiative has been previously described [4–6]. Briefly, AMD identified a set of quality-of-care indicators to be used for benchmarking activities. Quality indicators include process measures evaluating diagnostic, preventive and therapeutic procedures performed by the participating centers, and outcome indicators measuring favorable and unfavorable modifications in the patient health status. Furthermore, the use of glucose-lowering, anti-hypertensive, and lipid-lowering drugs is evaluated. Participating centers share an ad hoc software enabling the data extraction from different electronic medical records. Data are annually collected in a standardized format (AMD Data File) and centrally analyzed anonymously. Results are publicized through the publication of the analyses (AMD Annals volumes) and in a dedicated page of the AMD website [8]. Furthermore, using a specific software, each center can calculate its own indicators and compare its performance with the national average and that of the best performers.

2.1. Quality of care indicators

The number of quality indicators routinely measured in AMD Annals has progressively increased across the years. Process measures are expressed as percentages of patients monitored at least once during the index year for the following parameters: HbA1c, blood pressure (BP), lipid profile (LDL cholesterol, total and HDL cholesterol, and triglycerides), renal function (eGFR and albuminuria), foot examination, and eye examination.

Intermediate outcome measures include the proportion of patients with values reaching targets recommended by guidelines as well as the percentage of those with unacceptably high values. Outcomes are considered satisfactory if HbA1c levels are $\leq 7.0\%$ (≤ 53 mmol/mol), BP values are $< 130/80$ mmHg, and LDL cholesterol (LDL-c) levels are < 70 mg/dl. Unsatisfactory outcomes include HbA1c levels $> 8.0\%$ (> 64 mmol/mol), BP values $\geq 140/90$ mmHg, LDL-c levels ≥ 100 mg/dl, presence of micro-/macro-albuminuria, and glomerular filtration rate (eGFR) < 60 ml/min/1.73 m². Although selected outcome indicators may not reflect the targets recommended for all patients, they have been chosen to provide a synthetic picture of the care provided to large numbers of patients over the years. In this respect, the initiative tends to put major emphasis on unsatisfactory outcomes as a level for improvement.

Indicators of treatment intensity/appropriateness take into consideration the use of pharmacologic treatments in relation to the level of the clinical parameters: no insulin therapy despite HbA1c $\geq 9.0\%$ (≥ 75 mmol/mol), no lipid lowering agents despite LDL-c ≥ 100 mg/dl, no antihypertensive treatment despite BP $\geq 140/90$ mmHg, no ACE inhibitors (ACE-I) or angiotensin receptor blockers (ARBs) despite micro-/macroalbuminuria, HbA1c $\geq 9.0\%$ (≥ 75 mmol/mol) in spite of insulin treatment, LDL-c ≥ 100 mg/dl in spite of lipid-lowering treatment, and

BP $\geq 130/80$ mmHg in spite of antihypertensive treatment. Recently, the following treatment indicators have been added: no treatment with SGLT2-i and/or GLP1-RAs despite micro/macroalbuminuria, no treatment with SGLT2-i despite eGFR < 60 ml/min/1.73 m², no treatment with SGLT2i and/or GLP1-RA despite established cardiovascular disease, no treatment with SGLT2i despite heart failure.

Finally, a quality-of-care summary score (Q score) is calculated. The Q score has been developed and validated in two previous studies [9–10] and integrated in the AMD Annals initiative since the 2009 edition. The score is based on a combination of process and outcome indicators relative to HbA1c, blood pressure, LDL-c, and albuminuria. The score ranges between 0 and 40 and correlates with the 3-year risk of incident cardiovascular events (80% excess risk if score < 15 , and 20% excess risk if score between 15 and 25, compared to score > 25).

2.2. Statistical analyses

We report the most recent AMD Annals initiative results, relative to the index year 2022.

Study population was represented by all patients with diagnosis of T2DM recorded in EMR. In case of multiple records collected during the year for the same patient, the last available value was included in the quality of care profiling. The denominators for the different quality indicators vary according to the availability of the information in the index year. No missing imputation was performed.

Patients' characteristics were described as mean and standard deviation or frequencies. Quality indicators are expressed as crude percentages.

3. Results

3.1. Diabetes-related clinical characteristics of T2D patients included in the AMD Annals Initiative

Overall, 295 diabetes clinics extracted from their electronic clinical database the information relative to 502,747 patients with T2D seen in 2022; of these, 5.8% were first visits and 6.9% were new diagnoses. Table 1 shows clinical characteristics of T2D patients included in the current analysis.

The study population (56.8% men) had a mean age of 67.4 years, and about one in three patients had > 75 years. Diabetes duration was 12.9 years, and 17.6% were smokers.

Average HbA1c and BMI levels were 7.2% and 28.7 kg/m², respectively. As for lipid profile, mean LDL cholesterol levels were 86.8 mg/dl and mean triglycerides levels were 135.8 mg/dl. Mean BP values were 135.8 mmHg for systolic, and 76.9 mmHg for diastolic BP.

The prevalence of micro- and macrovascular complications is also reported in Table 1. Diabetic retinopathy was recorded in 12.8% of patients; micro/macroalbuminuria was recorded in 24.8% of patients; an eGFR < 60 ml/min/1.73 m² in 30.4%, and 0.3% were on dialytic treatment, respectively. Overall, 14.6% had documented cardiovascular disease (CVD), minor amputations were recorded in 0.4% of participants.

Lipid lowering and antihypertensive drugs were prescribed in $> 65\%$ of patients.

As for current diabetes treatments (Table 1), oral therapy alone (one or more oral agents) was prescribed to 47.1% of the patients, insulin treatment, alone or in combination with oral agents and/or GLP1-RAs, to 32.3% of the patients, and GLP1-RAs, alone or in combination with other antihyperglycemic agents, was prescribed to 27.5% of the patients.

Among glucose-lowering drugs, metformin (72.6%) was the most frequently used, followed by SGLT2-i (29.0%), GLP1-RAs (27.5%) and DDP4-i (21.0%) (Fig. 1).

Table 1

Diabetes-related clinical characteristics of T2D patients included in the AMD Annals Initiative.

Variables	N, mean \pm SD, or %
Number of participating diabetes clinics	295
Number of patients with T2DM seen by diabetes clinics during the year	502,747
Percentage of first visits (%)	5.8
Percentage of new diagnoses (%)	6.9
Patient characteristics	
Men (%)	56.8
Age (yrs)	67.4 \pm 13.5
Age >75.0 years (%)	31.1
Smokers (%)	17.6
Diabetes duration (yrs)	12.9 \pm 10.5
Risk factors	
HbA1c (%)	7.2 \pm 1.2
BMI (Kg/m ²)	28.7 \pm 5.5
BMI \geq 30 Kg/m ² (%)	37.1
Total cholesterol (mg/dl)	162.6 \pm 39.3
LDL cholesterol (mg/dl)	86.8 \pm 33.0
HDL cholesterol (mg/dl)	48.7 \pm 13.0
Triglycerides (mg/dl)	135.8 \pm 79.7
Systolic blood pressure (mmHg)	135.8 \pm 18.6
Diastolic blood pressure (mmHg)	76.9 \pm 10.2
Diabetes complications	
eGFR <60 ml/min (%)	30.4
Micro/macroadalbuminuria (%)	24.8
Diabetic retinopathy (%)	12.8
Established cardiovascular disease (%)	14.6
Minor amputations (%)	0.4
Major amputations (%)	0.1
Foot ulcer/gangrene in the index year (%)	0.4
Dialysis (%)	0.3
Current therapy	
Diabetes treatment (%)	
Diet and lifestyle	2.9
Any scheme including GLP1-RA	27.5
Oral monotherapy	21.5
Dual oral therapy	19.0
\geq Triple oral therapy	6.6
Insulin + Oral therapies	13.9
Insulin only	8.6
Lipid-lowering agents (%)	66.5
Antihypertensive treatment (%)	68.1

Data are mean \pm standard deviation or proportions.

Abbreviations: HbA1c: glycated haemoglobin; LDL-C: low-density lipid profile; HDL-C: high-density lipid profile; BP: blood pressure; BMI: body mass index; eGFR: estimated glomerular filtration rate (CKD-Epi formula); SGLT2i: Sodium-glucose cotransporter 2 inhibitors; GLP1-RA: Glucagon-like peptide 1 receptor agonists; DPPiV: dipeptidyl peptidase IV inhibitor.

3.2. Quality indicators of diabetes care

Fig. 2 shows the achievement of targets for major CVD risk factors, as recommended by current guidelines. Overall, HbA1c value \leq 7.0% was documented in 54.6% of patients, BP <130/80 mmHg in 23.0%, and LDL-c levels <70 mg/dl in 34.3%, but only 5.2% were at-target for all the risk factors.

Conversely, as shown in Fig. 2, 17.8% of the patients had HbA1c levels >8.0%, 30.7% showed LDL-c levels \geq 100 mg/dl, and BP values \geq 140/90 mmHg were found in 51.9% of patients.

Table 2 also reports several quality of diabetes care indicators relative to the year 2022.

In particular, process indicators refer to the proportion of patients who was monitored for major risk factors at least once during the year 2022, whereas indicators of intensity/appropriateness of treatment included the proportion of subjects not treated with a specific class of drugs in spite of a clear recommendation, or the proportion of patients reaching unsatisfactory risk factors values despite being on the appropriate treatment.

Overall, process measures were satisfactory as for the monitoring of

HbA1c, lipid profile, blood pressure, and renal function. Lower percentages of patients had eye or foot examination.

Assessment of treatment intensity/appropriateness showed that the proportions of patients not treated with insulin, SGLT2-i, or GLP1-RAs despite unsatisfactory values of HbA1c or despite the presence of renal or CVD complications ranged from 10.5% to 73.4% for the different indicators. Furthermore, from 21.6% to 39.5% of patients were not treated with antihypertensive drugs, ACE-I and/or ARBs, lipid-lowering agents, or antiplatelets, despite an existing indication for their use.

Of note, 50.7% of patients with established CVD were treated with SGLT2-i or GLP1-RAs. Also, one in two patients with heart failure was treated with SGLT2-i, and one in two patients with albuminuria was treated with SGLT2-i or GLP1-RAs.

On the other hand, proportions of patients maintaining elevated and unsatisfactory values of HbA1c, LDL-c, or BP in spite of appropriate prescriptions ranged from 8.5% to 22.7% for the different indicators.

Finally, patients with a Q score lower than 15 (i.e., 80% excess cardiovascular risk) and with Q score between 15 and 25 (i.e., 20% excess cardiovascular risk) were 3.2% and 35.6%, respectively, while the largest proportion (61.2%) included patients with adequate Q score (>25).

4. Discussion

In Italy, T2D affects 3,5 million people [11], with a North-South gradient in its prevalence (4.6 vs 6.6%) [12], and estimates of a further growth, which is expected, related to the progressive ageing of the population, obesity trends and the impact of socio-economic variables [13].

Healthcare service in Italy is state-funded, and diabetes care is primarily provided by a large network of diabetes clinics, in addition to general practitioners. The AMD Annals data is provided by 1/3 of these clinics, which share the same electronic medical records system and a specific software for anonymous data extraction, thus guaranteeing the representativeness of the study sample.

The current data show a picture of the actual status of T2D care provided by these centers in Italy.

Thus, the good rate of monitoring of HbA1c and other outcome and process measures, with the only exception of retinopathy and foot examination, likely reflects that T2D patients included in the current analysis regularly attended specialist diabetes centers.

This picture also shows that these T2D patients are overall elderly subjects, overweight /obese and with a long diabetes duration; 1/3 of them had microvascular disease, and any CVD was documented in >15% of subjects, figures that are similar to those previously reported in the T2D Italian population by the Renal Insufficiency And Cardiovascular Events (RIACE) study [14].

Moreover, according to the Verona Diabetes study, CVD is responsible for 42% of mortality of Italian T2D patients [15], and the CAPTURE study, conducted on a large cohort of T2D subjects from 13 countries, including Italy, showed that it was largely accounted for by atherosclerotic CVD [16,17].

A recent sub-analysis from the AMD Annals also showed that among 473,740 T2D participants, 78.5% were at very high cardiovascular risk, 20.9% at high risk and only 0.6% at moderate risk, according to ESC CVD risk categories [18].

Despite the enormous burden of CVD risk associated with T2D, our current updated analysis of the AMD Annals data showed that many patients do not meet recommended targets, nor are they appropriately treated according to current national and international guidelines yet [1,19].

When evaluating the achievement of recommended targets for major risk factors, we found that half of T2D subjects had HbA1c value \leq 7.0%, and only 1/4 of them were at-target for BP, and 1/3 for LDL-C.

A 2018 meta-analysis on data from 20 countries also documented the insufficient rate of achievement of risk factors control, with pooled

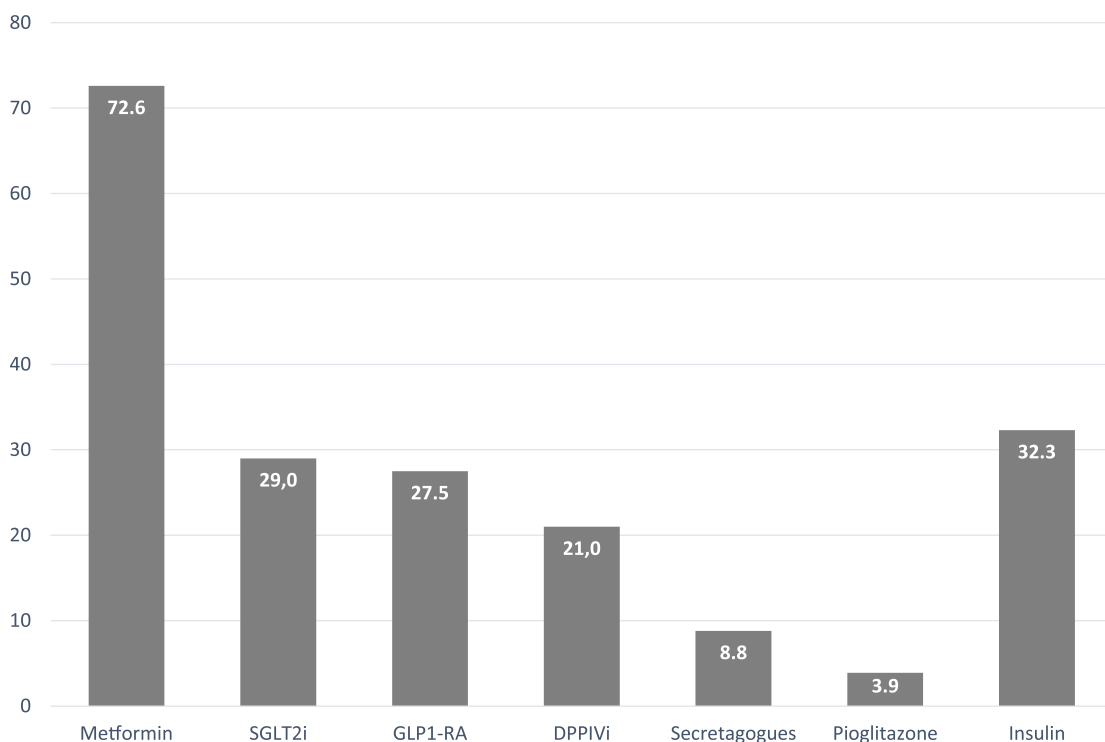


Fig. 1. Prevalence of use of glucose-lowering drug classes.

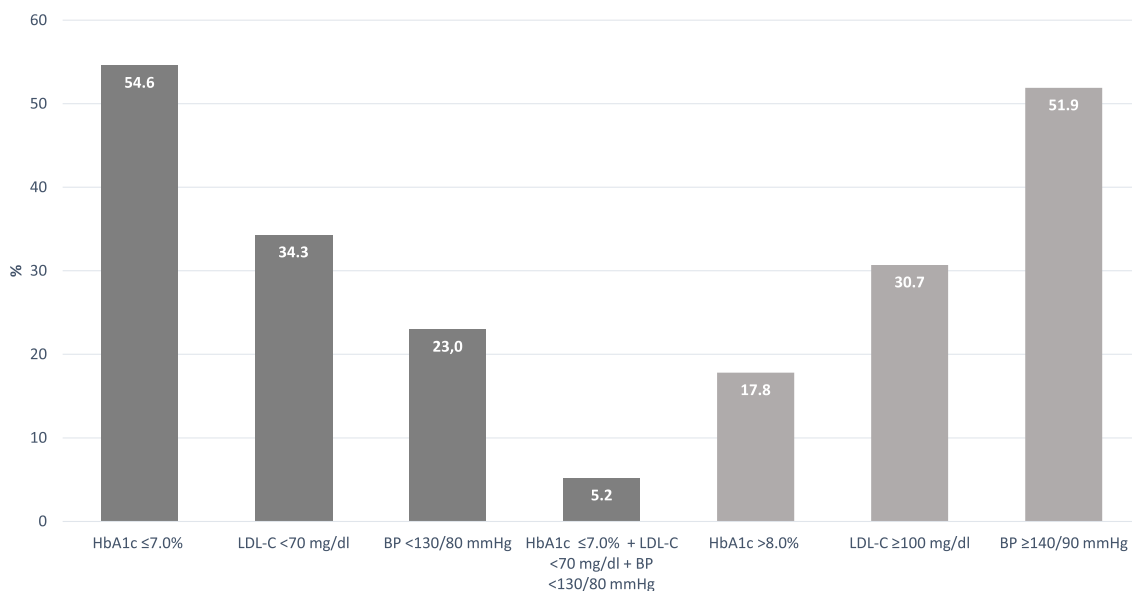


Fig. 2. Favorable and unfavorable intermediate outcome indicators of diabetes care.

target achievement rates that were of 42.8% for glycemic control, 29.0% for BP, and 49.2% for LDL-c [20]. The reasons behind the global failure to achieve glycemic control, as well as lipid and BP targets, are multifactorial and the more stringent targets imposed by guidelines and poor adherence to medications are certainly among them; also, the lack of awareness regarding diabetes management and self-care, as well as therapeutic inertia, are crucial factors that have long been recognized [21,22].

A European epidemiological study involving GPs investigated the clinical patterns associated with the lack of achievement of several risk factors targets, indicating younger age, obesity, long diabetes duration

and presence of CVD as significant predictors [23].

Although attaining recommended targets is fundamental to reduce the risk of micro- and macrovascular complications, current guidelines still recommend that therapeutic goals should be tailored based on individual's preferences and characteristics, including age, frailty, life expectancy, diabetes duration, comorbidities and complications [1,19], all factors that may influence T2D management. In this regard, we should underline that T2D patients included in the AMD Annals Initiative were elderly, with one in three patients having >75 years, and this may have important clinical implications when interpreting our data on achieved targets and treatment patterns.

Table 2

Quality of diabetes care indicators in T2D patients included in the AMD Annals Initiative.

List of indicators	%
Process indicators (% of patients who during the year 2022 received at least)	
1 HbA1c measurement	95.7
2 HbA1c measurements	49.2
1 lipid profile evaluation	78.8
1 blood pressure	84.3
1 albuminuria evaluation	66.9
1 creatinine evaluation	91.6
Foot examination	14.9
Eye examination	27.1
Indicators of treatment intensity/appropriateness (% of patients not treated despite unsatisfactory values or presence of specific complications)	
Not treated with insulin despite HbA1c $\geq 9.0\%$ (>75 mmol/mol)	30.5
Not treated with insulin, SGLT2i, and/or GLP1-RA, despite HbA1c $\geq 9.0\%$ (>75 mmol/mol)	10.5
Not treated with SGLT2i and/or GLP1-RA despite micro/macrobalbuminuria	47.2
Not treated with SGLT2i despite eGFR <60 ml/min	73.4
Not treated with SGLT2i and/or GLP1-RA despite established cardiovascular disease	40.3
Not treated with SGLT2i despite heart failure	50.7
Not treated with lipid-lowering agents despite LDL-c ≥ 100 mg/dl	25.3
Not treated with antihypertensive treatments despite BP $\geq 140/90$ mmHg	30.0
Not treated with ACE-I and/or ARBs despite micro/macrobalbuminuria	39.5
Not treated with antiplatelets despite established cardiovascular disease	21.6
Indicators of treatment intensity/appropriateness (% of patients with unsatisfactory values despite the treatments)	
HbA1c $\geq 9.0\%$ (>75 mmol/mol) despite treatment with insulin	16.1
HbA1c $\geq 9.0\%$ (>75 mmol/mol) despite treatment with insulin, SGLT2i, and/or GLP1-RA	8.5
LDL-c ≥ 100 mg/dl despite lipid-lowering treatment	24.8
BP $\geq 130/80$ mmHg in spite of antihypertensive treatment	22.7
Overall quality of diabetes care (% of patients with Q-score <15; 15–25; >25)	
Q score <15 (80% excess CV risk)	3.2
Q score 15–25 (20% excess CV risk)	35.6
Q score >25 (reference class)	61.2

Data are proportions.

Abbreviations: HbA1c: glycated haemoglobin; LDL-C: low-density lipid profile; BP: blood pressure; BMI: body mass index; eGRF: estimated glomerular filtration rate (CKD-Epi formula); SGLT2i: Sodium-glucose cotransporter 2 inhibitors; GLP1-RA: Glucagon-like peptide 1 receptor agonists; CV: cardiovascular.

However, as for innovative drugs prescription, the progressive implementation in the use of GLP1-RAs and SGLT2-i, when compared to previous data collection referring to the years 2019–2020 (GLP1-RAs, 12.0% to 15.7%; and SGLT2-i 13.2% to 16.6%, in patients on telemedicine vs those on face-to-face consultation) [24], indicate that age is not perceived as a limitation by diabetologists, in accord with a growing body of evidence demonstrating that the CVD benefits of these drugs also apply to the elderly patients [25].

Moreover, this attitude is even more important in the light of the progressive impairment of renal function in the elderly population with T2D [26].

Thus, the 2022 AMD Annals data show that, overall, 29.0% of patients were on SGLT2-i, and 27.5% on GLP1-RAs. In particular, when considering modern indicators of appropriateness which are in line with updated guidelines, 59.7% of T2D individuals were treated with either GLP1-RAs or SGLT2-i among those with established CVD, 26.6% were treated with SGLT2-i among those with impaired renal function, and half of subjects were treated with SGLT2-i among those with heart failure.

Also, the progressive reduction in the use of secretagogues and insulin may be seen as a step forward in the slow and progressive path of improving clinical inertia, as witnessed by the AMD Annals Initiative overtime [27]. Thus, it is increasingly acknowledged that therapeutic inertia not only describes the lack of treatment intensification when goals are not met, but also the failure to de-intensify therapy in case of

overtreatment.

Since 2006, through the continuous monitoring and measuring of diabetes care, the AMD Annals initiative contributed to ameliorate therapeutic inertia and to the slow and progressive improvement of different and complex aspects involved in diabetes care, with a spread impact on a large part of Italian diabetes centers [6].

This progressive implementation has also been documented by the amelioration of the Q-score. Notably, today, only 3.2% of T2D patients showed a Q score <15 , which correlates with an 80% higher risk of 3-years incident CVD events (compared to scores >25), with $>60\%$ of patients having a Q-score >25 , indicating an adequate level of the overall diabetes care [9,10].

As for strengths and limitations, the major strength of the AMD Annals Initiative is represented by the study methodology, including the anonymous extraction, through a dedicated software, of clinical data recorded in electronic charts in the course of everyday clinical practice, being one of the largest and long-standing clinical datasets on T2D. Also, the representativeness of the sample size, involving 1/3 of diabetes clinics in Italy and the selection and the regular update of quality-of-care indicators should be considered.

The lack of information on mortality and socio-economic data, and the rate of missing data on some variables may be acknowledged among the limitations of the study.

5. Conclusions

Since 2006, the AMD Annals Initiative has constantly monitored diabetes quality of care in 1/3 of diabetes clinics in Italy, thus representing one of the largest clinical data collections on diabetes. This Initiative has witnessed the slow but constant improvement of T2D care overtime, showing trajectories and principal areas for future interventions in order to overcome clinical inertia. The 2022 AMD Annals data show an increasing use of new antihyperglycemic drugs, and a continuous improvement of overall quality of care. However, additional efforts are needed to increase the adherence to more stringent recommended targets relative to cardiovascular risk factors and metabolic control.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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